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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,964	07/08/2003	Hector F. DeLuca	1256-00777	8876

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EXAMINER
MCMILLIAN, KARA RENITA

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
09/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/614,964	DELUCA ET AL.	
	Examiner	Art Unit	
	KARA R. MCMILLIAN	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22* is/are pending in the application.

4a) Of the above claim(s) *1-21 and 23-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/25/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Status of Claims

Applicants have made no amendment to the claims. Claim 22 is currently pending.

Response to Arguments

Applicant's arguments filed May 4, 2007 have been fully considered but they are not persuasive.

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Assuming *arguendo* that applicant's arguments complied, the applicant's have taken the position that one of ordinary skill would not have chosen the claimed compound as it has less activity than related compounds. The examiner points out that claim 22 of the instant application is drawn to a compound that is broadly disclosed in the prior art. The applicant's have not argued against the fact that the compound is broadly disclosed in the prior art only a motivation for choosing the claimed compound based upon increased/decreased biological activity. The examiner points out that activity against VDR is only one example of increased/decreased biological activity.

Other factors such as increased solubility, bioavailability, toxicity oral bioavailability, etc… also factor into biological activity.

Regardless of the reasoning, the examiner has pointed out that the claimed compound has been broadly disclosed in the prior art, claim 22 of the instant application is drawn to a compound broadly disclosed in the prior art, and the applicant's have not argued that the compound is not disclosed.

The examiner respectfully points out the following: "Products of identical chemical composition can not have mutually exclusive properties. "A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties that applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The examiner respectfully points out the following from MPEP § 2112.01: "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

For the reasons set forth above and for reasons of record the 103(a) rejection of the last office action is maintained. This action is made FINAL.

The 103(a) rejection is included below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

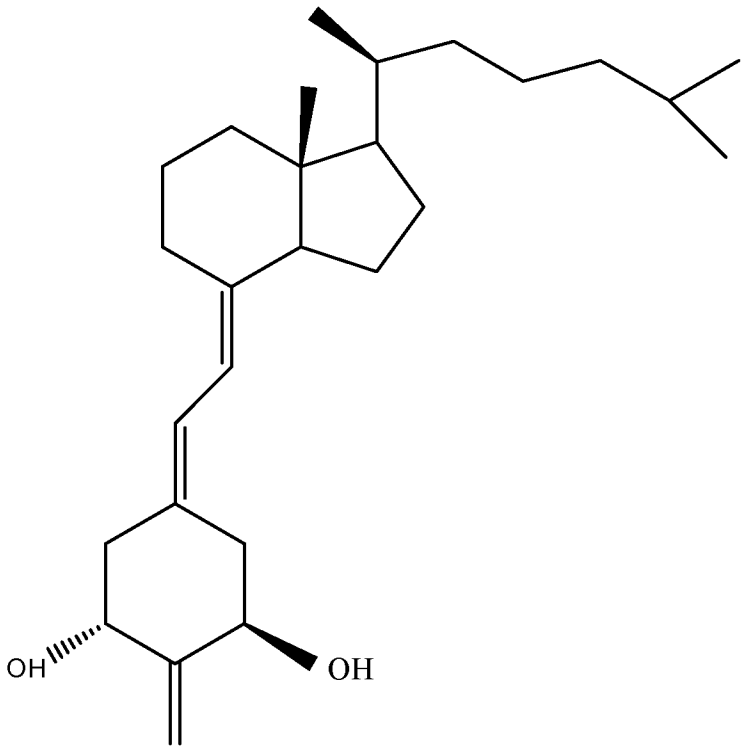
The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

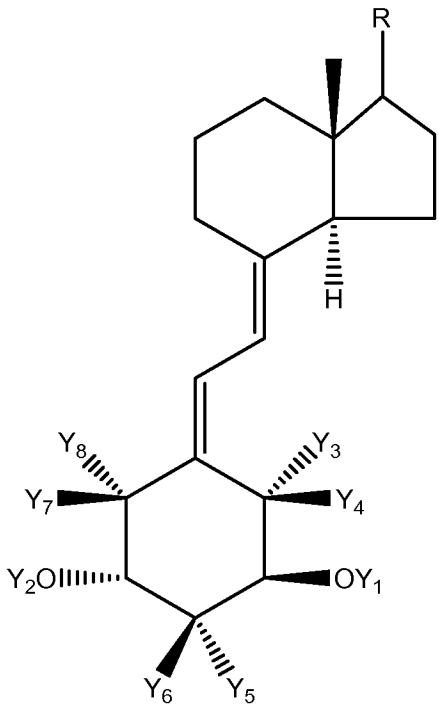
Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeLuca, et al. (US Patent No. 6114317).

Claim 22 of the instant application claims a compound (20S)-1α-hydroxy-2-methylene-19-nor-vitamin D_3 having the formula:



DeLuca et al. teach, in the abstract, a method of modifying or altering the structure of a 1α-hydroxylated vitamin D compound to increase its biological activity. DeLuca et al. teach, in col. 4 line 66 to col. 6 line 44, novel 1a-hydroxylated vitamin D analogs of formula I. Specifically in col. 4 line 66 to col. 6 line 44 it is stated:

"Structurally these novel analogs are characterized by the general formula I shown below:



where Y_1 and Y_2, which may be the same or different, are each selected from the group consisting of hydrogen and a hydroxy-protecting group; where Y_3, Y_4, Y_5, Y_6, Y_7 and Y_8, which may be the same or different, are each selected from the group consisting of hydrogen, a methyl group or substituted methyl group of the formula --CR_1 R_2 R_3, an amino group or substituted amino group of the formula --NR_1 R_2, a phosphino group or substituted phosphino group of the formula --PR_1 R_2, an alkylsulfinyl group, an arylsulfinyl group, an alkylsulfonyl group, an arylsulfonyl group, and aryl, where R_1, R_2 and R_3 are each independently selected from the group consisting of hydrogen, C_{1-5} alkyl, hydroxyalkyl, aminoalkyl, halogenalkyl, alkoxyalkyl, aryloxyalkyl, aryl, halogen, hydroxyl, protected hydroxy, alkoxyl, aryloxyl, acyl, an amino group, an alkyl substituted amino group, and an aryl substituted amino group, and where R_1 and R_2 taken together represent an oxo group or a group --$(CH2)_m$ -- where m is an integer having a value of

from 2 to 5; or Y3 and Y4 when taken together represent a methylene group; or Y7 and Y8 when taken together represent a methylene group; where Y_2 and Y_6, or Y_2 and Y_7, when taken together may represent the group --(CR1 R2)$_n$ -- where n is an integer having a value of from 1 to 4 and wherein any of the groups --CR_1 R_2 -- may be replaced by an oxygen, sulfur or nitrogen atom; where Y_5 and Y_8, or Y_5 and Y_3, or Y_3 and Y_8, when taken together may represent the group --(CR_1 R_2)$_r$ -- where r is an integer having a value of from 1 to 5 and wherein any of the groups –CR_1 R_2 -- may be replaced by an oxygen, sulfur or nitrogen atom; and where Y_5 and Y_6 when taken together represent the group =CR_4 R_5 where R_4 and R_5, which may be the same or different, are each selected from the group consisting of hydrogen and Y_3, with the proviso that R_4 and R_5 cannot be a hydroxyl; and where R_4 and Y_2 when taken together may represent the group --(CR_1 R_2)$_s$ -- where s is an integer having a value of from 1 to 3; and where the group R represents any of the typical side chains known for vitamin D type compounds.

More specifically R can represent a saturated or unsaturated hydrocarbon radical of 1-35 carbons, that may be straight-chain, branched or cyclic and that may contain one or more additional substituents, such as hydroxy- or protected-hydroxy groups, fluoro, carbonyl, ester, epoxy, amino or other heteroatomic groups (see columns 5 and 6 for further structural details).

Formula I when Y_7, Y_8, Y_4, Y_3, Y_2, Y_1 are all Hydrogen, and Y_6 and Y_5 when taken

together represent the group $=CR_4R_5$ where R_4 and R_5 are hydrogen, and R is the 20S vitamin D_3 alkyl group then the currently claimed compound, (20S)-1α-hydroxy-2-methylene-19-nor-vitamin D_3 is achieved. Formula I is a genus to the particular species currently claimed. In col. 12 lines 3-30, the preferred analogs section entitled 10β-Substitution, DeLuca et al. exemplifies related compounds to the currently claimed compound with the difference being the presence of a 10β-substituent (U) which can be a methyl group etc…(see col. 9 lines 50-64).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to select the currently claimed compound as it is broadly disclosed in the genus of DeLuca et al. (as set forth above) and thus one of ordinary skill would expect it to posses increased biological activity as compared to 1α-hydroxylated vitamin D, as suggested by DeLuca et al. Further DeLuca et al. exemplify an embodiment that is closely related to the currently claimed compound (see above).

Conclusions

Claim 22 stands rejected. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARA R. MCMILLIAN whose telephone number is (571)270-5236. The examiner can normally be reached on Monday-Thursday from 8:30 am- 6:00 pm and every other Friday from 8:30 am- 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kara R. McMillian/
Examiner, Art Unit 1617

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/SREENI PADMANABHAN/
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